UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

THE HIPSAVER COMPANY, INC., Plaintiff, v. J.T. POSEY COMPANY, Defendant.	Civil Action No. 05-10917 PBS
AND RELATED COUNTERCLAIM.	

J.T. POSEY COMPANY'S OPPOSITION TO THE HIPSAVER COMPANY, INC.'S MOTION IN LIMINE TO EXCLUDE THE 2006 TAMPERE TEST AND TEST RESULTS

J.T. Posey Company ("Posey") opposes The HipSaver Company, Inc.'s ("HipSaver") motion *in limine* to exclude the 2006 Tampere test and test results. The Tampere Test is relevant to the issue of the truthfulness of the statement that "Posey Hipsters Help Prevent Against Injury From Falls". Posey's advertising does not claim that the Garwood testing supports this statement. Therefore, contrary to HipSaver's argument, the statement is not an establishment claim. Thus, the issue of whether the Garwood test supports this claim is a red herring.

As for the reliability of the testing, the Tampere testing of Posey's products was conducted using the same protocol by the same people who tested HipSaver's products and which HipSaver cites in support of its advertising claim that its products have been "proven effective" in "independent biomechanical test[ing]". The fact that HipSaver touts its products on the strength of testing at Tampere constitutes an implied admission that the Tampere testing is

trustworthy and that reports of Tampere testing have "circumstantial guarantees of trustworthiness". Thus, Posey's Tampere test results are admissible under Rule 807 of the Federal Rules of Evidence.

I. FACTS

HipSaver advertises on its website that its products have been "proven effective in [an] independent biomechanical test". The documentation HipSaver relies on to support this claim is available on its website. It consists of a report of some testing on its hip protector pads by Jari Parkkari and Jarmo Poutala of the Tampere University of Technology, Applied Mechanics Laboratory in Tampere, Finland. See attached Exhibit "A". The tests were performed using the same protocol and the same testing system the authors described in an article published in *Bone* 1999, Aug. 25(2):229-235. See attached Exhibit "B".

In 2006, Posey engaged Messrs. Parkkari and Poutala, i.e., the same people who tested HipSaver's pads, to conduct testing on the pads Posey uses in its Hipsters. The tests were performed using the same protocol and the same testing system the authors used to test HipSaver's products. (The test results are attached to HipSaver's motion as Exhibit "A".)

Despite the fact that it is standing behind its own Tampere tests results to support its claim that its products have been "proven effective" in "independent biomechanical testing", HipSaver now seeks to preclude Posey from using Tampere test results to support its claim that "Posey Hipsters Help Prevent Against Injury From Falls".

II. ARGUMENT

HipSaver presents two challenges to the Tampere Test, neither of which has any merit.

A. <u>The Posey Tampere Test Is Relevant to Posey's Claim That "Posey Hipsters Help Prevent Against Injury From Falls".</u>

As an initial matter, HipSaver argues that the Posey Tampere Test results are irrelevant to the truth or falsity of Posey's establishment claims, because the Posey Tampere Test was not cited in the accused advertisements and did not exist at the time of the advertisements. This argument is meritless for the simple reason that not all of the accused statements in Posey's advertising are establishment claims.

As an example, Posey's "Tight Rope Walker Flyer" states that "Posey Hipsters Help Prevent Against Injury From Falls". The flyer does not say, or even imply, that "tests prove that Posey Hipsters Help Prevent Against Injury From Falls". Thus, it is not an establishment claim. See Order on Summary Judgment Motions 5/15/07, at 24-25 [D.N. 228]. It is, at most, a statement of fact and HipSaver bears the burden of showing affirmatively that this statement is false. *See Clorox Co. Puerto Rico v. Proctor & Gamble Comm. Co.*, 228 F.3d 24 (1st Cir. 2000); *see also* Order on Summary Judgment Motions 5/15/07, at 24-25 [D.N. 228].

Since the Posey Tampere Test is directly relevant to the issue of the truth or falsity of at least one non-establishment claim, HipSaver's motion should be denied.

B. <u>The Posey Tampere Test Is Admissible Pursuant to FRE 807</u>

HipSaver's second argument in support of its motion is that, even if Posey's Tampere test results are relevant, they constitute inadmissible hearsay. In making this argument, HipSaver conveniently ignores Federal Rule of Evidence 807 which provides, in pertinent part, that:

> A statement not specifically covered by Rule 803 or 804 but having equivalent circumstantial guarantees of trustworthiness, is not excluded by the hearsay rule, if the court determines that (A) the statement is offered as evidence of a material fact; (B) the statement is more probative on the point for which it is offered than

> any other evidence which the proponent can procure through reasonable efforts; and (C) the general purposes of these rules and the interests of justice will best be served by admission of the statement into evidence.

Here, the Posey Tampere Test has circumstantial guarantees of trustworthiness equivalent to those statements covered by Federal Rule of Evidence 803 or 804. The Posey Tampere Test was produced in the ordinary course of business by a laboratory that HipSaver characterizes on its website as "prestigious". Moreover, in documentation available on its website, HipSaver further avers that "[t]he research group affiliated with this laboratory is currently most active in the development and biomechanical testing of hip protectors and has several published reports on the subject."

Finally, the testing system and the protocol utilized in the Posey Tampere test was the same as the one the Tampere researchers used in testing HipSaver's hip protector pads. And, as HipSaver is fond of pointing out, and as discussed in the Posey Tampere Test, the protocol and testing system used were published in a peer reviewed journal. See Exhibit "A" to Plaintiff's Motion. Because the parties have used the same scientists, the same University, the same protocol and the same testing system, HipSaver should not be heard to complain about the trustworthiness of Posey's Tampere Test.

As for the individual elements specified by Rule 807, the Posey Tampere Test is offered as evidence of a material fact, namely, that Posey hipsters help protect against injury from falls which is an issue raised by HipSaver. The Tampere test shows that Posey's hip pads dramatically attenuate the force transmitted to the hip bone in a fall which constitutes strong evidence that Posey Hipsters do, in fact, help protect against injury from falls.

The Posey Tampere Test is also the most probative evidence Posey can procure through reasonable efforts. The alternative to admitting the test would be to require Posey to produce the

two researchers who conducted the test. Since they are in Finland, such a burden would obviously be unreasonable.

Finally, the general purposes of the Federal Rules of Evidence and the interests of justice will best be served by admission of the Posey Tampere Test into evidence. *See* Fed. R. Evid. 102 (the rules of evidence shall be construed to secure fairness and the elimination of unjustifiable expense and delay). Since the tests on Posey's pads were conducted by the same individuals who tested HipSaver's pads using the same protocol and the same testing system, it would be manifestly unfair to permit HipSaver to cite its Tampere test results as evidence of the effectiveness of its products, but to deny Posey the same right.

Notwithstanding all of the foregoing, Posey notes that under Rule 703 of the Federal Rules of Evidence, Posey's expert can rely on Posey's Tampere test results regardless of whether this Court finds that the report of the test results is admissible because the tests were based on a protocol and testing system cited in an article published in a peer reviewed journal. Thus, the question of the admissibility of the Tampere test report may well be moot.

III. CONCLUSION

For the forgoing reasons, this Court should deny Plaintiff's motion to exclude the 2006 Tampere test and test results.

Dated: May 22, 2007

J.T. POSEY COMPANY

By its attorneys,

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CERTIFICATE OF SERVICE

I certify that this document has been filed through the Electronic Case Filing System of the United States District Court for the District of Massachusetts and will be served electronically by the court to the Registered Participants identified in the Notice of Electronic filing.

May 22, 2007

/s/ Donald K. Piper
Donald K. Piper

EXHIBIT "A"

Interpretation of Biomechanical Testing of HipSaver® Dual-mechanism Shunting/Absorbing AirPad

August 2000

Background: HipSaver pads were tested at the Harvard affiliated laboratory in 1996 and found to offer 10% better impact attenuation than SafeHip® (SafeHip is the product resulting from the initial research efforts as reported in *The Lancet* 1993 341:11-18). Since then HipSaver has researched a variety of materials with various attributes for potential incorporation into the HipSaver product. In August 2000, the selected construction (HSPE4 12.7mm) was sent to the Tampere University of Technology Applied Mechanics Laboratory for impact testing on a mechanical hip system. The research group affiliated with this laboratory is currently most active in the development and biomechanical testing of hip protectors and has several published reports on the subject.

HipSaver Pad Construction: HipSaver encloses a 1/2" (12.7mm) thick damping foam material in a waterproof/air tight pouch. The pads taper down to 1mm at the edge. The pouch is either RF or heat sealed around the perimeter. Pad diameters are 6.5 to 7.5 inches. These pads are sewn into polycotton underwear so as to overlie the trochanters.

Test Results: The test system and protocol are identical to that reported in *Bone* 1999 Aug. 25(2):229-35 (abstract enclosed). The pad being tested is affixed to a surrogate hip bone and then impacted by a swinging pendulum. Load cells capture the amount of force on the system. The test report on HipSaver shows the HipSaver pad (HSPE4 12.7mm) lowered a typical falling force of 7200N to below the fracture threshold of 3100N +/- 1200N. The following table compares the results from the HipSaver test to other pads tested in the *Bone* report (using the identical system and protocol):

Pad Id.	Description	7200N Fall Force Reduced to
KPH2	35mm height, polyethylene shell	760N
SafeHip	25mm height, polypropylene shell	2240N
Saftypants	20mm thick, low density polyethylene (soft)	2270N
HipSaver HSPE4	12.7mm thick, urethane foam in pouch (soft)	1790N

Conclusion: Only KPH2 and HipSaver reduced the applied force clearly below the fracture threshold of 3100N (+/- 1200N). A lower value on this test indicates better protective capacity since the values represent force REDUCTION. The above shows HipSaver to offer 20% more attenuation than Safehip.

The Damping Foam Absorbs the Shock and the Displaced Air Redistributes the Forces in the AirPad:
Although the HipSaver pad has the lowest profile (thinness) and is the softest, it performed remarkably well when compared to the stiffer and thicker pads. This result stems from the fact that the airtight pouch renders an "energy shunting" or diverting effect on the applied force: the initial impact is absorbed by the urethane foam and the displaced air from the foam inflates or distends the surrounding pouch. Hence, much similar to automotive air bag, the force is redistributed over a larger and softer area. This inflation effect can be demonstrated by pushing a HipSaver pad with the heel of the hand and observing the distention of the pouch. The HipSaver pad is thus a dual mechanism "shunting/absorbing" air pad.

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Trochanteric pad tests **HipSaver®**

Two thicknesses of the hip protector type HSPE4 were tested. The thickness of the thinner model was 8.4 mm, the thicker one was 12.7 mm. These pads were enclosed in waterproof nylon and polycotton knit material. These pad tests were performed at the midrange force of 7230N as per the protocol and the testing system described in ***Bone*** 1999 Aug. 25(2):229-35. The above-mentioned force was attenuated by soft tissue to the value of 5600 N, which match the average peak hip impact force measured in the muscle-relaxed state during in vitro falling tests (Robinovitch et al. 1991). Pad named PE30 (thickness 20 mm) was used to simulate the soft tissue and that pad was changed after every impact for a new one. Six impact tests were done for every pad type. Then the force measurements were filtered and evaluations of averaged peak values and standard deviations were calculated to get the maximum compressive impact forces as seen in Table 1. Typical time-dependent test curves of both thicknesses are seen in Figure 2.

Table 1 Averaged trochanteric impact forces and their standard deviations.

Speed	Energy	HSPE4 8.4 mm		HSPE4 12.7 mm	
		Mean kN	Std kN	Mean kN	Std kN
1.9 m/s	74 Nm	2.51	0.071	1.79	0.067

Description of facilities and the calibration

The data acquisition system is based on Microstar Laboratories Data Acquisition Processor DAP 3200A. The DAP 3200A has the DPL operating system.

The acquired data were analyzed by Matlab, which is used to numeric computation and visualization. The Matlab is a trademark of Math Works.

The sampling time was 10 μs. The number of acquired points was 1500 for each test curve. Known pads were used to see the same impact force level as reached in the tests earlier. The test system is seen in Figure 1.

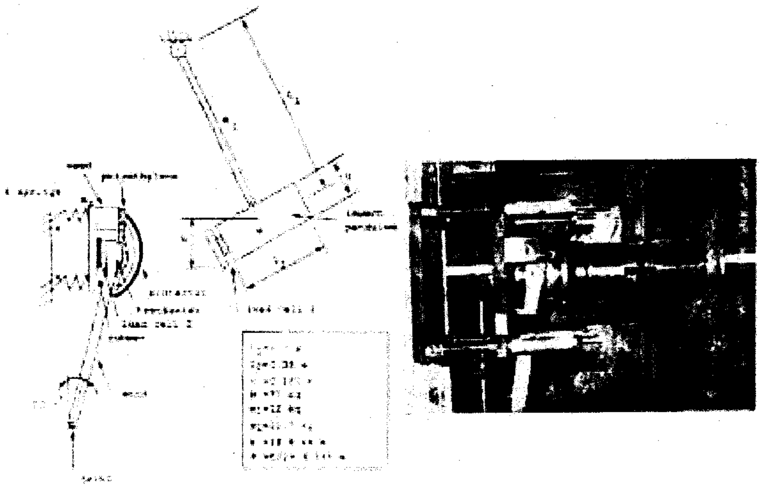

Figure 1 The hip protector testing system.

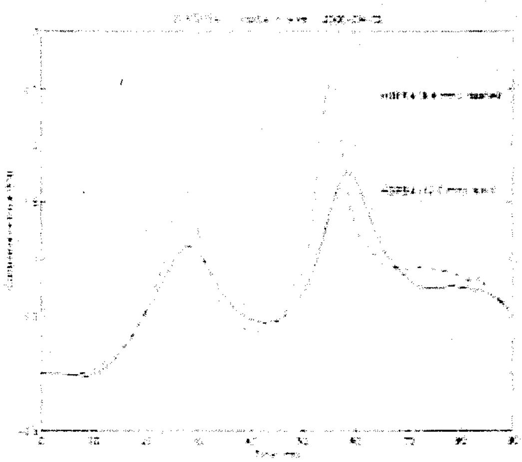

Figure 2 Test curves for the third impact of HSPE4 of the both thicknesses.

Tampere 2000-09-15

Jarmo Poutala, Laboratory Manager

EXHIBIT "B"

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Comparison of Force Attenuation Properties of Four Different Hip Protectors Under Simulated Falling Conditions in the Elderly: An In Vitro Biomechanical Study

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The purpose of this in vitro biomechanical study is to determine the force attenuation capacity of four different hip protectors (KPH1, KPH2, Safehip, and Safetypants) in falling simulations in elderly subjects (falls to the side). The simulated falling conditions were created by a biomechanical testing system, which consisted of an impact pendulum, surrogate pelvis and femur, and two load cells. Three series of impact experiments were conducted in an ascending order (low, moderate-, and high-force experiments), each exceeding the literature-provided average (±1 SD) fracture threshold (3100 ± 1200 N) of the proximal femur of elderly women with a mean age of 71 years. Using a low impact force of 4330 N, the trochanteric soft tissue (20-mm-thick polyethylene foam) attenuated the peak femoral impact force to 3740 N and, accordingly, the KPH1 protector to 590 N, KPH2 to 510 N, Safehip to 1080 N, and Safetypants to 790 N. Thus, in this low force experiment, all tested protectors could reduce the peak impact force entered into the proximal femur below the aforementioned average fracture threshold area (3100 ± 1200 N) of the proximal femur of elderly women. With a moderate impact force of 7230 N, the soft tissue attenuated the peak femoral impact force to 6130 N, and the protectors to 780 N, 760 N, 2240 N, and 2760 N, respectively. Thus, with this impact force, only the KPH hip protectors could reduce the impact force clearly below the fracture threshold area. In the final series of the experiment, the peak femoral impact force was set to be so high (10,840 N) that the protector, if effective, should prevent the hip fracture in almost all cases and situations. The trochanteric soft tissue attenuated this peak impact force to 9190 N, and the tested protectors to 1360 N, 1170 N, 4640 N, and 5770 N. Thus, with the KPH protectors the force received by the proximal femur remained below the average force required to fracture the proximal femur of elderly women, whereas with the two other protectors the impact force entered into the proximal femur clearly exceeded this threshold value. In conclusion, the test results showed that, of the four tested hip protectors, the anatomically designed energy-shunting and energy-absorbing KPH protectors can provide an effective impact force attenuation in a sideways-fall simulation in the elderly, whereas the force attenuation capacity of the two other protectors seems more limited. However, the true efficacy of any protector in the prevention of hip fractures can only be evaluated in randomized clinical trials. (Bone 25:229–235; 1999) © 1999 by Elsevier Science Inc. All rights reserved.

Key Words: Elderly; Falls; Hip fracture; Fracture prevention; Hip protectors; Biomechanical testing.

Introduction

Hip fractures among the elderly are a worldwide epidemic and the incidence of such fractures is expected to rise dramatically as populations age.[4,16,20,26,27,30,31,39] In addition to high costs, these fractures are associated with high morbidity and disability, high risk for long-term institutionalization, and increased risk of death.[3,8,19,21,29,48]

In the pathogenesis of the hip fractures, the falling mechanism, the impact energy created by the fall, the energy absorption capacity of the trochanteric soft tissue, and bone strength have been suggested to be the main determinants of fracture.[9,14,15,17,18,22,23,25,35,36,44] Two prospective studies by Greenspan et al.[13,14] suggest that, among the elderly, the characteristics of the fall are even more important determinants of hip fracture than bone mineral density of the hip, although the latter also has an independent role in the pathogenesis of this injury.[7,13,14,33] Most hip fractures seem to be caused by a sideways fall with direct impact on the greater trochanter of the proximal femur.[7,9,13,14,18,22,23,35,36,46] One fourth of such falls cause hip fractures, whereas fewer than 2% of all falls cause this injury.[9,24,34,50]

Trochanteric soft tissue thickness is linearly correlated to the body mass index (BMI).[28] Experimental studies have, in turn, shown that the soft tissue covering the hip improves energy absorption during a fall,[22,45] and, in this way, allows less energy to be transmitted to the proximal femur. These findings may partly explain the reduced risk of hip fracture in elderly women who are overweight.[14,18,22,45]

The great majority of hip fractures occur in the elderly in whom bone mineral density is already below the theoretical fracture threshold.[13,14] In these individuals, the success of interventions aiming at improvements in bone mass and density may be limited, whereas interventions directed at factors unrelated to

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bone mass might be worth consideration. In fact, it has been reported that external hip protection may halve the risk of hip fracture.[24]

In the 1980s and early 1990s several attempts were made to characterize the force attenuation capacity of external hip-padding systems.[22,47,54] However, these early experiments did not use realistic, precisely determined impact forces and conditions. More recently, Robinovitch et al.[43] tested the force attenuation capacity of seven hip-padding systems under simulated fall-impact conditions. The greatest reduction in peak femoral impact force was provided by an energy-shunting pad (65% reduction) and this property was clearly better than the force reduction provided by the best energy-absorbing pad (about 33% reduction). At the same time, Parkkari et al.[40] also determined the force attenuation properties of a number of different trochanteric padding materials using simulated impact energies and taking into account the effective mass, stiffness, and damping of the body during the impact. Their findings suggested that, using reasonable thicknesses of various hip-padding materials, it was impossible to lower femoral impact force to below the theoretical fracture threshold.

In the first phase, the aforementioned observation of Parkkari et al.[40] resulted in the development of an energy-shunting hip protector (KPH hip protector, Finnish Red Cross Orthopaedic Service, Helsinki, Finland) that would effectively attenuate and shunt away from the greater trochanter the impact energies created in the typical sideway falls of elderly individuals, and then, in the second phase, in determination of the force attenuation capacity of the device in simulated (in vitro) falling conditions of the elderly.[38] The biomechanical test results showed that the padded, dome-shaped polyethylene shield of the KPH protector indeed provided an effective impact force attenuation in fall-to-the-side simulations in the elderly.[37,38] Later, to further improve user compliance, the convexity of the shield was somewhat lowered, and the new shield modification was named the KPH2 hip protector.

The purpose of this study is to compare the force attenuation properties of the new KPH2 hip protector with the original KPH1 protector, as well as with two other well-known and similarly commercially available hip protectors, Safehip (Sahva A/S, Copenhagen, Denmark) and Safetypants (Raunomo, Tampere, Finland). No previous study has made such a biomechanical comparison between commercially available hip protectors.

Materials and Methods

Testing System

The testing system consisted of the impact pendulum, surrogate pelvis and femur, and two load cells, and has been described in detail elsewhere (Figure 1).[38,40] The effective mass of the pendulum was 40.3 kg (effective mass = $1/3 \times m_1 + M$; see Figure 1), simulating the effective mass of the body during impact to the hip. The surrogate pelvis was designed to match the typical stiffness and damping of a female pelvis.[38,40] The effective mass of the surrogate pelvis was 11.7 kg. Pelvic compliance was simulated with four steel springs (k = 18.8 kN/m) with an effective stiffness of 75 kN/m. The wooden surrogate femur has the size and shape of a female femur. The major and minor axes of the trochanter, modeled as an ellipsoid, were 35 mm and 25 mm. A load cell (Kistler 9065, Winterthur, Switzerland) and a piece of rubber (k = 100 kN/m) matching the hip joint stiffness were mounted between the surrogate pelvis and the femur. The angle between the pelvis (vertical line) and femur was 10.5°. A second load cell was positioned at the impacting end of the pendulum (Figure 1).

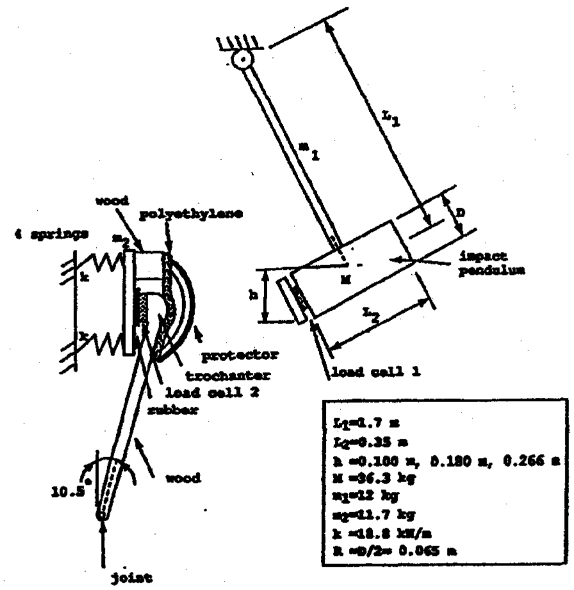

Figure 1. The hip protector testing system. The insert gives the exact values for the terms of the figure. The height of the impact pendulum (D) was 0.13 m, and its half (R = 0.065 m) was used to determine the center of the gravity, and thus the descent height of the pendulum (h).

The surrogate pelvis was also designed to match the typical surface topography and local soft tissue stiffness of the female pelvis. The 20-mm-thick polyethylene foam or "soft tissues" covered the surrogate pelvis. Its thickness was selected so that it would attenuate about 15% of the peak femoral impact force, the attenuation matching that of an elderly woman's soft tissues of the hip.[43,45]

The impact forces were measured with the aforementioned load cells (Figure 1): load cell 1 recorded the impact force at the impact end of the pendulum, and load cell 2 the impact force entering into the proximal femur. The signals were amplified (Kistler 5001) and the data were collected by an IBM Pentium microcomputer using a DAP 3200e A/D card (Microstar Inc.) as a data-acquisition processor. The digitized data were not subjected to a smoothing procedure, and the peak impact value was determined automatically by the software of the microcomputer (and visually verified from the impact curve). The data sampling interval was 10 µsec.

Protectors Tested

KPH1 hip protector. The original KPH1 hip protector was designed to cover the greater trochanter and to both shunt the impact energy away from the greater trochanter and partly absorb the impact energy during the fall on the hip (Figure 2).[38] The majority of the impact energy was designed to be shunted to and absorbed by the soft tissues lying anterior, posterior, and superior to the proximal femur. The inferior contact of the protector was designed to be on the femoral shaft.

The length of the protector is 19.0 cm, and the maximum width 9.0 cm. Maximum height in the middle of the device is 4.5 cm. The outer shield is made of semiflexible 3-mm-thick high-density polyethylene and the inner energy-absorbing part of 12-mm-thick Plastazote (Fagerdala World Foams, Termonova Inc., Inkoo, Finland), the most efficient energy absorbing mate-

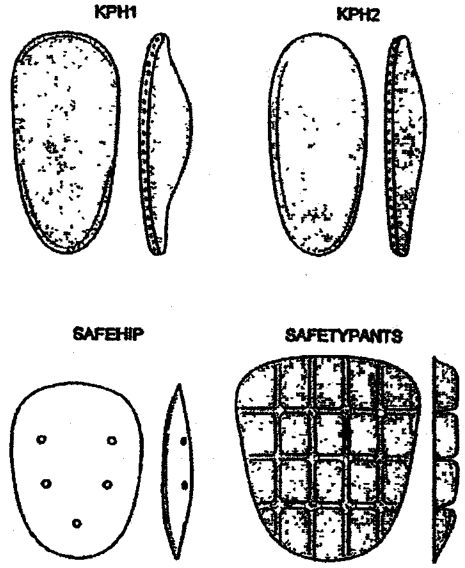

Figure 2. Frontal and side-view drawings of the four hip protectors tested.

rial in the previous test.[40] Plastazote is a soft and resilient material with a closed cellular structure and low weight.[40] The shape of the protector has been designed to mimic anatomically the surface topography of the female pelvis using the hips of six ambulatory older women (aged 65, 73, 80, 82, 87, and 91 years) as models.[38] The protector has been shaped to be intentionally more convex than the topography of the women's trochanteric region, clearly leaving space (safety margin) between the skin that lies over the tip of the greater trochanter and the corresponding inner part of the protector. While wearing the protector, this margin of safety has been measured to be 2.0–2.5 cm in these women with markedly varying body composition (weight ranging from 40 to 70 kg).[38] This amount of safety margin is thought to be enough to prevent contact between the trochanter and the outer shield of the protector in the falling situation, with the protector thus shunting the impact energy to the tissues surrounding the proximal femur. In the surrogate pelvis experiment, this margin of safety was set to be 2.0 cm; that is, less than or equal to the margin in a clinical situation.

In clinical practice, the shields of the KHP1 protector are placed in the pockets of a specially designed undergarment.

KPH2 hip protector. Later, to further improve the elderly's acceptability and compliance for regular use of an energy-shunting hip protector, the convexity of the polyethylene shield of the KPH1 hip protector was lowered somewhat so that the maximum height in the middle of the KPH2 device is 3.5 cm (4.5 cm in the KPH1) and the aforementioned margin of safety 1.0–1.5 cm, respectively. The length of the KPH2 is 19.0 cm (i.e., no change) and the maximum width is 8.5 cm (KPH1 9.0 cm). Otherwise, the KPH2 does not differ from the KPH1.

Safehip. According to the manufacturer, the Safehip protector shell also has the ability to cover the greater trochanter of the proximal femur and both divert the impact energy away from the trochanter area and partly absorb the impact energy of falling.[51] The length of the dome-shaped Safehip protector is 15.4 cm, and the maximum width 11.0 cm. The maximum height in the middle of the device is 2.5 cm (Figure 2). The Safehip protector shell has a grained surface, is made of relatively flexible 9-mm-thick polypropylene foam, and has an internal reinforcing member or core made of the same, but higher density, polypropylene. The protector has five perforations (diameter 5 mm). In clinical practice, the protector shells are placed in the pockets of a specially designed undergarment.

Compared with the KPH protector, the Safehip protector is more rounded, less curved (convex), and clearly more flexible.

Safetypants. Safetypants has 20-mm-thick low density polyethylene foam (i.e., the previously noted Plastazote) as the hip-protecting padding material (Figure 2). The length of the pad is 18.0 cm and the maximum width 16.0 cm. In clinical practice, the pads are placed directly over the greater trochanter of the femur in the pockets of specially designed underpants, thus leaving no space or margin of safety between the skin of the greater trochanter and the inner part of the pad. The purpose of these paddings is thus to absorb the impact energy of the fall so effectively that the fall-induced force entering into the proximal femur would remain below the fracture threshold.

Impact Experiments

Three series of impact experiments were conducted to measure the force attenuation provided by the four protectors. In all experiments, the effective mass of the pendulum was 40.3 kg.

In the first "low energy" or "low impact force" experiment, the pendulum descent height (h) was 0.10 m, the hip impact velocity 1.4 m/sec, and the impact energy 41 J. The corresponding peak hip impact force of this calibration hit was measured to be 4330 N. The soft tissue (polyethylene foam) of the surrogate pelvis was measured to attenuate this peak impact force by 13.6%. Thus, the peak force that entered into the surrogate proximal femur was 3740 N, which is, as reported by Cheng et al. in their large biomechanical study,[1] above the average force required to fracture an elderly woman's proximal femur in a typical fall-loading condition (3100 N), and also above the avarage fracture threshold of the proximal femur of elderly women reported by other, similar investigations (2900–3400 N).[2,6,49] Six consecutive impacts were given on each device. The surrogate soft tissue was replaced after every impact.

In the second "moderate energy" or "moderate impact force" experiment, the pendulum descent height was 0.18 m, providing an impact velocity of 1.9 m/sec and an impact energy of 74 J. The peak impact force of this calibration hit was measured to be 7230 N. The soft tissue attenuated this force to 6130 N (15.2%), which is somewhat above the average peak hip impact force (5600 N) measured in the muscle-relaxed state during in vitro falling tests[42] and clearly above the aforementioned average fracture threshold of the proximal femur of elderly women. As in the first experiment, six consecutive impacts were given on each of the four devices and the surrogate soft tissue was replaced after every impact.

In the third "high energy" or "high impact force" experiment, the pendulum descent height was increased up to 0.266 m, providing an impact velocity of 2.3 m/sec, similar to the hip impact velocities measured in human volunteers falling on their hip.[53] The hip impact energy was 110 J. In the calibration hit, the peak impact force was measured to be 10,840 N, matching the hip impact force measured in the muscle-active state of an in vitro falling condition.[42] The soft tissue attenuated this force to 9190 N (15.2%). Thus, in this final experiment, the peak femoral impact force was set to be so high that the protector, if effective, should prevent the hip fracture in almost all subjects (also including the most dangerous fallers; i.e., those with low bone

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mineral density and bone strength, as well as those who are tall and heavy and fall from the standing height or higher). Again, each protector was tested with six consecutive hits and the soft tissue was replaced after every impact.

The testing system was calibrated before and after each set of experiments. The results are reported as means and their 95% confidence intervals (95% CI), the 95% CI being similar to an α level of 5% and $p < 0.05$.[12] In this statistical method, the definition and calculation of a 95% CI for a mean are the same as those of the conventional $p < 0.05$ in the traditional statistical approach of hypothesis testing, but the major difference between these two methods is that the method of estimation used does not test (and then accept or reject) any preset hypothesis, but rather estimates the precision or reliability of the result obtained with the confidence interval and allows the researcher to interpret the clinical relevance of the result (in this study, the protector-to-protector difference in the force attenuation capacity). Because in this study only a limited, beforehand-decided number of hip protectors (four) were tested with limited, beforehand-decided levels of impact energies (three), confidence intervals of no higher than 95% were used.

Results

In the low, moderate, and high force experiments, the 95% confidence interval of the mean impact force of any of the four tested hip protectors did not exceed the mean of the other protectors, thus indicating that all the protector-to-protector differences were statistically significant (**Figure 3A–C**). Clinically and biomechanically, however, the force attenuation capacity of the KPH1 and KPH2 protectors did not differ from each other to important degree, whereas they both did clearly better than the other two protectors (Figure 3A–C). A sample of an actual time series of the impact data is given in **Figure 4A–D**.

The test results of the first or low force impact experiment are shown in Figure 3A. With the impact force of 4330 N (calibration impact), the trochanteric soft tissue (20-mm-thick polyethylene foam) attenuated peak femoral impact force to 3740 N and, accordingly, the KPH1 protector to 590 N, KPH2 to 510 N, Safehip to 1080 N, and Safetypants to 790 N. Thus, in this low force experiment, the KPH hip protectors did better than the two other protectors, although they all could reduce the peak impact force entered into the surrogate femoral neck to below the average (± 1 SD) fracture threshold of the proximal femur of elderly women (3100 $\pm$ 1200 N).

The results of the second or moderate force impact experiment are shown in Figure 3B. With used impact force of 7230 N (calibration impact), the trochanteric soft tissue attenuated peak femoral impact force to 6130 N. With this force the KPH1 and KPH2 protectors could reduce the impact force clearly to below the aforementioned average (± 1 SD) fracture threshold (to 780 N and 760 N, respectively), whereas with both the Safehip (2240 N) and Safetypants (2760 N) the impact force entered into the femoral neck was already within the average ± 1 SD fracture threshold area (gray area in Figure 3B).

The results of the third or high force impact experiment are shown in Figure 3C. With the impact force of 10,840 N (calibration impact), the trochanteric soft tissue attenuated peak femoral impact force to 9190 N. With this high force the KPH1 and KPH2 protectors could still reduce the impact force to below the aforementioned average (± 1 SD) fracture threshold (to 1360 N and 1170 N, respectively), whereas with both Safehip (4640 N) and Safetypants (5770 N) the impact force entered into the surrogate femoral neck clearly exceeded this threshold.

Discussion

A hip protection system can attenuate the impact force delivered to the proximal femur in a fall by either absorbing the impact energy with the pad material, or shunting the energy away from the greater trochanter into the surrounding tissues, or by both of these mechanisms.[36,38] The objective of the present study was to compare the force attenuation properties of four (and, by these force attenuation principles, clearly different) hip protectors in sideways-fall simulations in the elderly, providing low, moderate, and high force impacts on the protectors. The results indicate that, with low impact forces, all protectors tested could reduce the peak impact force entered into the surrogate proximal femur to below the mean (± 1 SD) fracture threshold of the proximal femur of elderly women,[1,2,6,49] whereas, with moderate-to-high impacts, the KPH1 and KPH2 protectors gave clearly better results than the Safehip and Safetypants (Figure 3B, C). Of the latter two protectors, the Safehip did somewhat better than the Safetypants, although both of them were within the average (± 1 SD) fracture threshold area already with the moderate force impacts.

The very good testing results of the KPH protectors can be understood by their firm and adequately convex structure (Figure 2). The force attenuation characteristic of the KPH protectors relies mostly on the energy-shunting approach; that is, the anatomically designed outer shield of the protector shunts a great amount of the impact energy away from the greater trochanter into a larger area of the surrounding pelvis and femur. In addition, the most efficient available energy-absorbing material[40] is attached to the shield of the protector so that the KPH protectors also operate via simple energy absorption of the impact energy. The Safehip protector is, in turn, less curved and clearly more flexible than the KPH protectors and, most likely, these differences explain its poorer force attenuation properties (Figure 3). According to a recent biomechanical analysis by Mills,[32] the Safehip-type protectors could absorb more energy safely if they were thicker, or if the shell design was modified.

The Safetypants protector differs considerably from the other protectors by relying on absorption of the impact energy only. Unfortunately, both the previous studies[40,43] and the current experiment clearly demonstrate that, in many fall situations, the 20-mm-thick hip padding cannot reduced the fall-induced impact force to below the fracture threshold. A previous study indicated further that the padding materials must be 100–140 mm thick to go below the aforementioned average (± 1 SD) fracture threshold area, an unrealistic demand in clinical practice.[40]

In the current study, the local soft tissue on the surrogate trochanter was selected so that it would attenuate about 15% of the peak femoral impact force. However, it must be remembered that there may be great variation in the thickness and energy absorptive capacity of the soft tissue covering the hip.[28] In addition, there are no reliable data concerning the age-related changes in the viscoelastic properties of soft tissue. On the other hand, all testing-system-related factors were similar for all protectors and held constant in each series of experiments, thus allowing reliable protector-to-protector comparison.

The impact forces used were selected from previous studies[42,52,53] and our preliminary measurements to be as realistic as possible for simulating characteristic falling conditions in older adults. Again, it must be kept in mind that the effective mass and falling velocity (thus the impact energy and force) may vary considerably from individual to individual and, in one individual, from fall to fall. In the final set of the present experiments, the impact force was selected to be so high (10,840 N) that the tested protector, if effective, could prevent hip fracture in almost all individuals and fall situations.

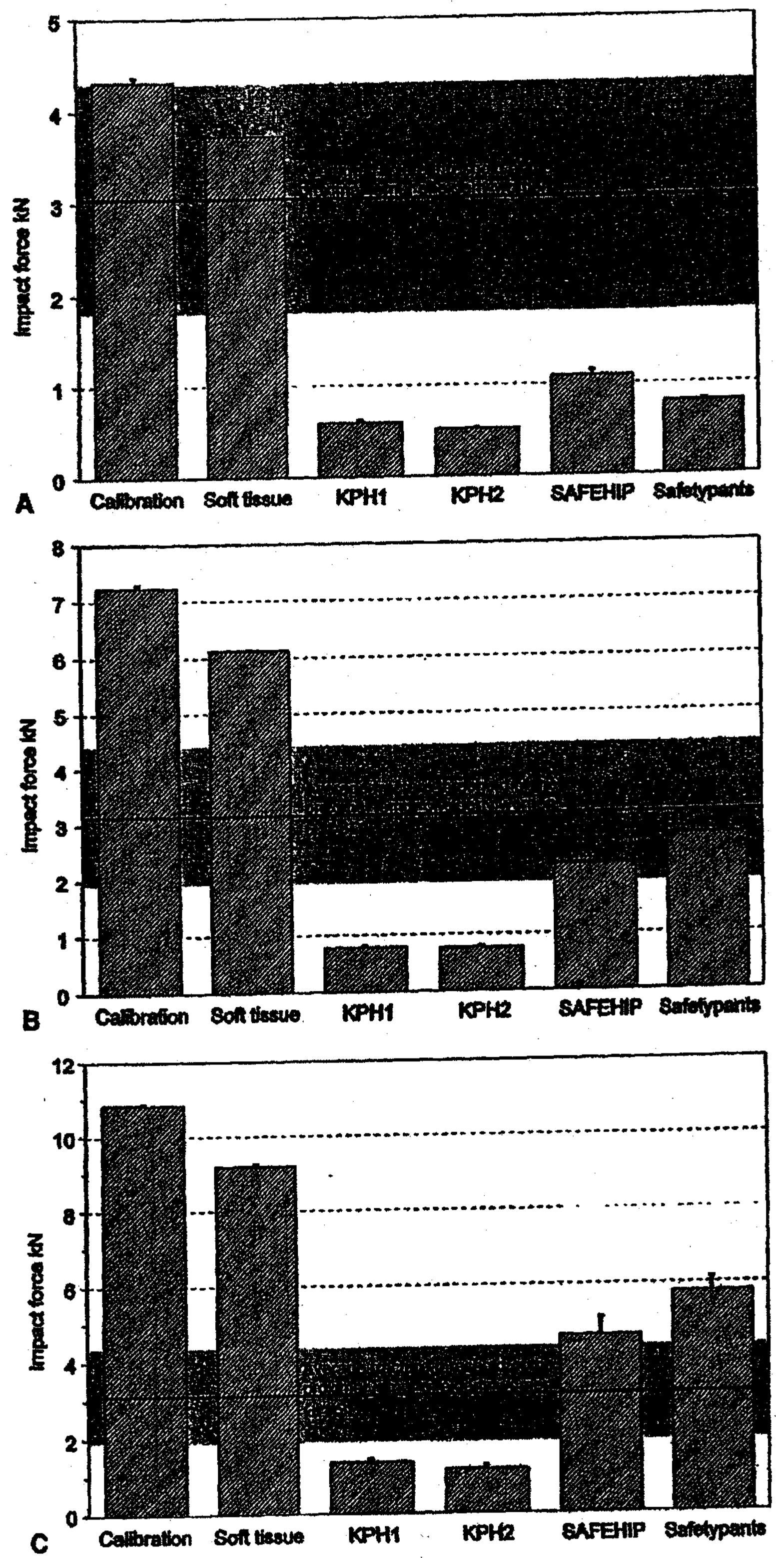

Figure 3. Biomechanical testing of four different hip protectors at: (A) low impact force; (B) moderate impact force; and (C) high impact force (impact forces entered into the surrogate proximal femur). The calibration column refers to impacts that were performed without the surrogate soft tissue and the protector, the soft tissue column to impacts performed with the surrogate soft tissue (i.e., force attenuation provided by the 20-mm-thick polyethylene foam), and the protector columns to impacts performed with the soft tissue and the protector in question. Bars represent the 95% confidence intervals of the means of six consecutive hits. The surrogate soft tissue was replaced after every impact. The horizontal line indicates the average (±1 SD) force required to fracture in vitro the proximal femur of elderly women in a typical fall-loading configuration of the hip. Asterisks: From Cheng et al.[1]

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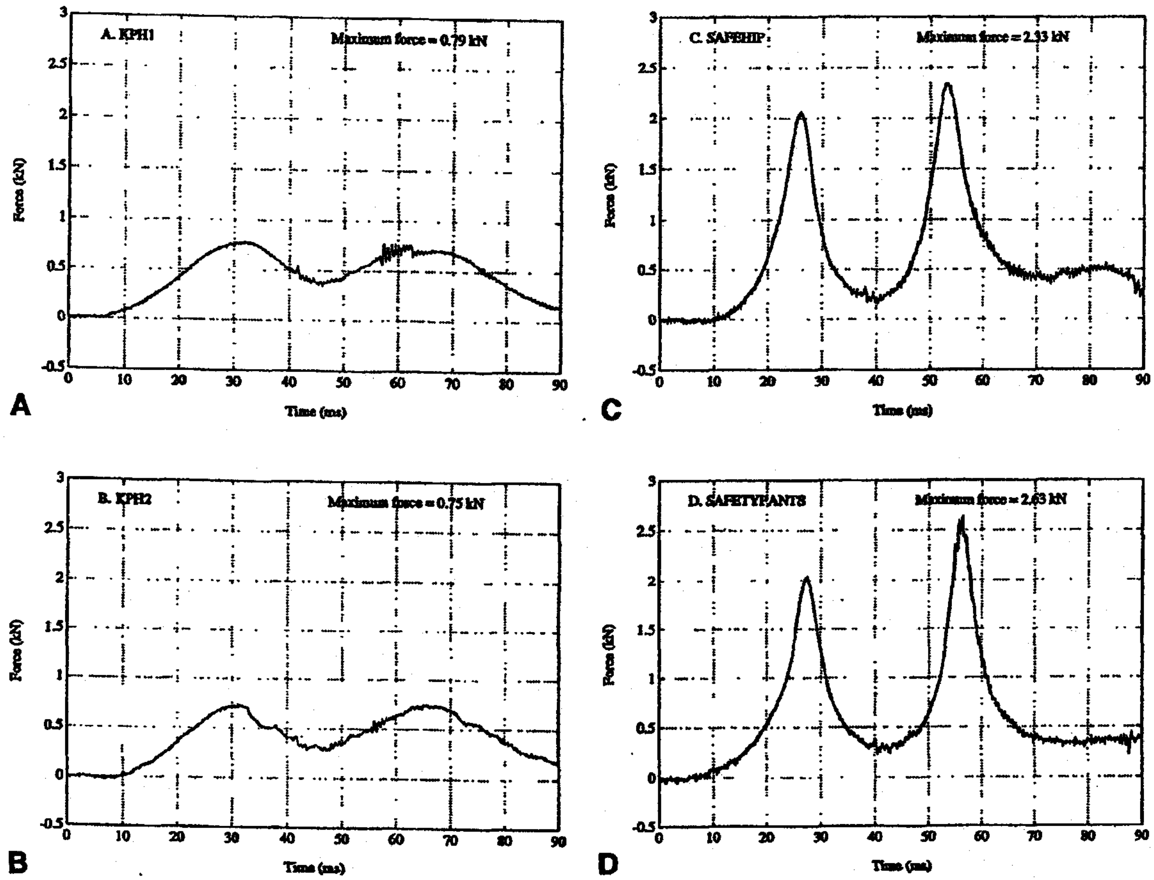

Figure 4. A sample of an actual time series of the impact data of the second or moderate-energy experiment (the pendulum descent height 0.18 m, impact velocity 1.9 m/sec, and impact energy 74 J). (A) KPH1 hip protector. (B) KPH2 hip protector. (C) Safehip hip protector. (D) Safetypants hip pads.

No complete protection of the hip can be taken for granted even when using an external protector. All protectors tested were designed to attenuate impact to the trochanteric area of the hip and thus their results have limited relevance to falls that may fracture the hip by other mechanisms, such as indirect rotational injuries. However, the latter mechanisms are likely to play a minor role in the pathogenesis of hip fractures, because recent studies have shown that impact near the hip clearly dominates the hip fracture risk in elderly who fall.[7,9,13,14,18,22,33,35,36,46] The energy-shunting protectors may influence the risk of other fractures, such as pelvic ring or femoral shaft fractures, and this must be investigated further. In the study by Lauritzen et al., the hip protector did not increase the incidence of other fractures.[24]

In this study, the femoral fracture threshold was set to 3100 N, which has been found to be the average force required to fracture an elderly woman's proximal femur under simulated fall-loading conditions.[1,2,6,49] However, it must be recalled that this fracture threshold will vary between individuals depending on the structural and material properties of the proximal femur, the falling mechanism (the position and angle of the greater trochanter at the time of impact), and the rate of loading.[5,6,11,41]

In conclusion, the current study has shown that, of the four hip protectors tested, the anatomically designed energy-shunting and energy-absorbing KPH hip protectors can provide an effective impact force attenuation in a fall-to-the-side simulation in the elderly. In this respect, the two other commercially available hip protectors seem to function less effectively. Finally, however, the true efficacy of any protector in the prevention of hip fractures must be evaluated in a randomized clinical trial.

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